

EXECUTIVE SUMMARY

State, local, and federal agencies currently use various methods to estimate risks to human health from the consumption of chemically-contaminated, non-commercial fish. A 1988 survey, funded by the U.S. Environmental Protection Agency (EPA) and conducted by the American Fisheries Society, identified the need for standardizing the approaches to evaluating risks and developing fish consumption advisories that are comparable across different jurisdictions (RTI, 1990). Four key components were identified as critical to the development of a consistent risk-based approach: standardized practices for sampling and analyzing fish, standardized risk assessment methods, standard procedures for making risk management decisions, and standardized approaches to risk communication (RTI, 1990).

To address concerns raised by the survey respondents, EPA is developing a series of four documents designed to provide guidance to state, local, regional, and tribal environmental health officials responsible for issuing fish advisories. The documents are meant to provide guidance only and do not constitute a regulatory requirement. The documents are:

Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories

Volume 1: *Fish Sampling and Analysis*

Volume 2: *Risk Assessment and Fish Consumption Limits*

Volume 3: *Risk Management*

Volume 4: *Risk Communication*

Volume 1 was released in September, 1993. Volume 4 is scheduled for release in 1995 and Volume 3 for 1996. It is essential that all four documents be used together, since no single volume addresses all of the topics involved in the development of risk-based fish consumption advisories.

The objective of *Volume 2: Risk Assessment and Fish Consumption Limits* is to provide guidance on the development of risk-based meal consumption limits for 23 high-priority chemical fish contaminants (target analytes). The target analytes addressed in this guidance series (See Table 1-1) were selected as particularly significant fish contaminants by EPA's Office of Water, based on their occurrence in fish.

their potential for bioaccumulation, and their toxicity to humans. The criteria for their selection are discussed in Volume 1 of this series. In addition to a presentation of consumption limits, Volume 2 contains a discussion of risk assessment methods used to derive the consumption limits, as well as a discussion of methods to modify these limits to reflect local conditions. Additional sources of information are listed for those seeking a more detailed discussion of risk assessment methods.

Earlier drafts of Volume 2 have been reviewed by experts at the federal, state, tribal, and local levels. Their input was used to revise the document to make it more useful and informative to public health professionals. For example, Volume 2 contains many refinements of the previous guidance *Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish: A Guidance Manual* (U.S. EPA, 1989a), including the addition of consumption limit tables and detailed toxicity data on the target analytes.

Part I of this document contains the information needed to use and modify the consumption limit tables provided for the 23 target analytes. The tables list a number of alternative consumption limits for each target analyte, based upon different meal sizes, contaminant levels, risk levels, and toxicity endpoints. Specific consumption limits have been developed, and are presented separately, for young children and adults in the general population. In addition, consumption limits specifically targeted to women of reproductive age have been developed for methylmercury. Information is also provided on methods for calculating consumption limits for multiple species diets and for multiple contaminant exposures.

Part II contains an overview of the current EPA risk assessment methodology used to derive the recommended meal consumption limits. This includes a discussion of the four main steps of the risk assessment: hazard identification, dose-response evaluation, exposure assessment, and risk characterization. Detail has been added on the toxicity of the target analytes, including new information on developmental toxicity. EPA risk values (chronic Reference Doses and cancer potency factors) from sources such as EPA's Integrated Risk Information System (IRIS) and the Office of Pesticide Programs are provided, with a discussion of supporting dose-response data.

The information in this document may be used in conjunction

with contamination data from local sampling programs and fish consumption surveys (or from consumption data provided in Volume 3), to select or calculate risk-based consumption limits for contaminated non-commercial fish. The consumption limits may be used with other types of information (e.g., cultural and dietary characteristics of the populations of concern, social and economic impacts, and health issues, including benefits of fish consumption and accessibility of other food sources) to establish health advisories. The decision-making process for the development of advisories will be discussed in the risk management document in this series (Volume 3).

In keeping with current EPA recommendations, discussions of uncertainty and assumptions are included in each section of the document. Although information was sought from a variety of sources to provide the best available data regarding the development of fish advisories, limited data exist for some critical parameters (e.g., toxicological properties of certain chemicals, and susceptibilities of specific population subgroups such as the elderly, children, and pregnant or nursing women). Although substantial toxicological information is available for all target analytes discussed in this document, readers are cautioned to always consider the methods and values presented in the context of the uncertainty inherent in the application of science to policies for safeguarding the general public from environmental hazards.

EPA welcomes your suggestions and comments. A major goal of this series is to provide a clear and usable summary of critical information necessary to make informed decisions regarding the development of fish consumption advisories. These documents are being prepared in binder form so that individual sections may be revised and replaced as significant new information becomes available. We encourage comments, and hope this document will be a useful adjunct to the resources used by states, local governments, and tribal bodies to make decisions regarding the development of fish advisories.